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Insider Insights: **Jubilant Clinsys**

CWWeekly's *semi-monthly company profile feature, Insider Insights, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with Nayan Nanavati, chief executive officer of Jubilant Clinsys.*

Q Unlike most American CROs, Jubilant Clinsys is part of a large diversified pharmaceutical services provider. As a small to mid-sized CRO that caters to the biotech community, which likes your access to India and parent company services, how are you competing against larger CROs?

A There are only a few CROs in the world that can provide more diversified discovery and development than us. We are very unique in the CRO industry. We provide services from comprehensive drug discovery to clinical development and post marketing research. Additionally, our capabilities in clinical informatics and technology set us apart from the rest. Nevertheless, we are very much aware that Jubilant Clinsys is a small to mid-sized CRO with unrealized potential, unique capabilities and values.

As it relates to competing against large CROs, it is not easy to compete in the current market environment. It may even get tougher for some time unless small to mid-sized CROs are prepared and fully capable of adjusting to the market dynamics that exist right now.

Q What is your strategy to distinguish your CRO operations from rivals and at the same time use the strengths of your large parent company in India? How do you see mid-sized CROs prospering in a changing market?

A Our strategy is to "adjust to the market dynamics" to effectively compete in the CRO market. Firstly, we focus on providing "value and performance partnerships" for our very targeted clients, specifically biotech and mid-sized pharmaceuticals, while we continue to provide services to large pharmaceutical companies for their post-marketing research services. Post-marketing research services often are not included in the strategic alliances with large CRO partners. Also, we remain optimistic with regard to the biotech sector. With the return of biotech funding, we have seen an increase in requests for proposals from more biotech and mid-sized pharmaceutical clients within the last few months.

Secondly, we offer our fully-integrated and combined discovery and development services through our Jubilant Discovery and Development group. We are already seeing great success with this strategy, as we have discovery and development strategy alliances with several very well-recognized academic institutes, as well as with biotech and pharmaceutical companies including three of the top 10 pharmaceutical companies.

Thirdly, we will enhance and diversify our existing capabilities. We have 70 dedicated employees in our state-of-the-art clinical informatics services. We intend to integrate and enhance our clinical informatics services to carry out effective, efficient and dynamic solutions for cost-effectiveness research, which is becoming very relevant in the U.S.

We also intend to enhance our EDC platform to support our post-marketing initiative. We will augment our bioanalytical services offerings to include novel biomarker analysis services during clinical trials. These are just a few of several areas in which we plan to focus in the short term. Our niche and value-added service offerings are going to be the thrust of our growth.

I strongly believe that small to mid-sized CRO market share will remain steady and may grow in the near future. However, to grow, small to mid-sized CROs must proactively

Jubilant Clinsys

Headquarters: Bedminster, N.J. A division of Jubilant Life Sciences, based in India.

Year Founded: 1992 (as Target Research Associates)

Description: A therapeutically-focused CRO that provides a range of clinical research services supporting phase I-IV drug and device development, including project management, clinical monitoring, scientific and medical support, investigator and patient recruitment, site management, biostatistics, data management, quality assurance, regulatory affairs and medical writing. Therapeutic areas include oncology, cardiovascular, central nervous system, dermatology, respiratory and allergy/immunology.

Officers: Nayan Nanavati, CEO;
Rahul Devnani, Senior Vice President, Finance, Contracts and Proposals and Information Technology;
Larry Veal, Executive Director, Business Development and Marketing

Operations: 44 countries

Offices: Bedminster, N.J.; Raleigh, N.C.; Ontario, Canada; Dusseldorf, Germany; Noida and Bangalore, India

Employees: 406 worldwide including 108 in the U.S.

Customers: 47

Web site: www.clinsys.com

and decisively respond to emerging market conditions and be prepared to change their course as warranted.

Q The recent consolidations within the clinical trials industry are putting pressure on CROs that need to get larger to win global business from both medium and large pharmas and biotechs. How do you see this changing landscape, and does your growth strategy include acquiring U.S. and European CROs?

A In my view, two distinctly different service CRO models will emerge in the industry: the super-global full-service CROs, and the smaller niche CROs focused on providing services to startups, emerging specialty firms and small to mid-sized pharma companies.

Furthermore, although not publicized much, a new strategic partnership model is emerging. This is where pharmaceutical and biotech companies of all sizes and constructs are transferring their assets—specifically their target molecules—to their strategic partners for discovery and development services through the end of phase II trials and beyond. There is enough evidence to suggest that this strategic drug discovery and development outsourcing model is maturing very fast.

Now let me address the notion of CROs getting large to win business. One does not necessarily need to get big to compete and grow. We need to "get smarter." We will compete and grow as a specialist CRO with a substantial competitive advantage by filling in gaps with complementary services, therapeutic competencies and added integration of technology, including clinical informatics for clinical trials.

We will amplify our strong presence in India and add competencies to support our operations. We are also actively looking at expansion in the Asia Pacific region. We already have strategic partnerships with various CROs in this region. We are considering forming a strategic partnership or a strategic joint venture in Latin America with a goal of creating a symbiotic relationship that will benefit both parties and allow value to be created at a faster rate than could be achieved independently.

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Nayan Nanavati, chief executive officer, Jubilant Clinsys

Q As trials become more global, sponsors seek speed, lower costs and treatment-naïve patients. What will you do to preserve and grow your U.S. clinical trials business—not just in the number of trials but in seeking new ways to recruit patient volunteers?

A It is generally understood that small to mid-sized CROs are better able to provide more cost-effective solutions than the big CROs simply because we do not have the overhead costs associated with larger CROs. Furthermore, we are in a better position to create a trial-specific solution to execute that trial effectively. We do not have a "one-size-fits-all" or clinical trial factory-type operation mind set. This streamlined and customized solution allows us to provide superior cost and operational solutions for our partners.

As for recruiting treatment-naïve patients, which is challenging the entire industry, we have implemented a Gold Star Site Network program. It has been in existence for several years and has been used in various therapeutic areas. We have exclusive relationships with investigators in the U.S. and many other parts of the world. They have consistently demonstrated exceptional performance and the ability to recruit treatment-naïve patients in an expeditious manner.

Even in very difficult circumstances we have been able to consistently deliver timely recruitment, and in many cases exceed patient recruitment timelines. We have also incorporated clinical intelligence into our patient recruitment efforts. Through our clinical informatics capabilities we are in a position to analyze and target certain patient populations in various parts of the country for different diseases based on epidemiology and reimbursement data.

Q After spending your career in the pharmaceutical industry and nearly 12 years at Parexel International as a corporate vice president and general manager, what lessons, experiences and leadership strategies are you bringing as CEO of a relatively little-known CRO?

A Parexel is a superb organization, and I learned a lot from it. During my tenure there, I learned many business elements that can be applied to a smaller CRO. Parexel taught me how to work in a service industry and how to respectfully cater to our clients. This is an important lesson for any CRO executive. I have learned to find value for our clients with every engagement we have with them. I have also learned to manage proactively and be able to change with the market dynamics.